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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,142	03/01/2002	Lakshmi Rambhatle	093/005P	3039
22869	7590	04/07/2004	EXAMINER	
GERON CORPORATION 230 CONSTITUTION DRIVE MENLO PARK, CA 94025			TON, THAIAN N	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,142	RAMBHATLA ET AL.	
	Examiner	Art Unit	
	Thai-An N Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/1/02.                      6) ☐ Other:

Art Unit: 1632

### DETAILED ACTION

Claims 1-16 are pending and under current examination.

#### *Information Disclosure Statement*

Applicants' IDS, filed 3/1/02, has been considered.

#### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, 7, 9, 10, 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-28 of copending Application No. 10/001,267. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of differentiating pPS cells into cells that have the morphological features of hepatocytes. The instant claims are directed to

Art Unit: 1632

methods for producing hepatocytes by culturing pPS cells in a medium containing a histone deacetylase inhibitor, and in particular embodiments, n-butyrate. The '142 claims are directed to hepatocyte cell populations and methods of producing the hepatocyte cell populations by culturing pPS cells in the presence of a hepatocyte differentiation factor, in particular n-butyrate. Accordingly, the instant claims are rendered obvious in view of the '267 claims, because they both recite the same methods of differentiating pPS cells in the presence of the same differentiating factor, n-butyrate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 14-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6, 23, 24, 25 of U.S. Patent No. 6,506,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods for screening compounds for hepatocellular toxicity. The instant claims are directed to methods of screening a compound for hepatocellular toxicity by combining a cell differentiated from pPS cells and determining if the compound is toxic to the cell. The '574 claims are directed to methods of screening a compound for its effect on hepatocytes or hepatocyte activity by combining the

Art Unit: 1632

compound with a cell population obtained by differentiating pPS cells. Accordingly, the instant claims are rendered obvious in view of the '574 claims.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, recite the term “~” in line 1 of the claim. It is unclear what the metes and bounds of “~” are. Claims 3-16 depend from claims 1.

The term "about" in claims 3-4 about is a relative term which renders the claims indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what the metes and bounds of the term “about” are.

Claim 9 recites the limitation "the stem cell line" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 9-11 depend from claim 9.

Claim 13 recites the limitation "the stem cell line" in line 1. There is insufficient antecedent basis for this limitation in the claim.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneko *et al.* [*Cancer Res.*, 50:3101-3105 (1990)].

The claims are directed to cell populations comprising at least 60% differentiated cells that are progeny of pPS cells and have the following characteristics: antibody-detectable expression of AAT, antibody-detectable expression of albumin, absence of antibody detectable of alpha-fetoprotein, RT-PCR detectable expression of ASGR, evidence of glycogen storage, evidence of cytochrome p450 activity, evidence of glucose-6-phosphatase activity; and the morphology of hepatocytes. In further embodiments, the claims are directed to methods of screening compounds for hepatocellular toxicity by combining the cell with a compound and determining if the compound is toxic to the cell.

Kaneko teach Chang liver cells, which were established from normal human hepatocytes [see p. 3101, 2<sup>nd</sup> column, *Materials*] were cultured in butyrate [see p. 3102, 1<sup>st</sup> column, *Results*, 2<sup>nd</sup> ¶]. Kaneko further teach that the liver cells were cultured in the simultaneous presence of novobiocin and butyrate and the cells

Art Unit: 1632

stoped proliferating and changed into fibroblast-like cells. See Abstract and *Results*, p. 3102.

Note that any human cell would be differentiated from pPS cells or human ES, as required by the claims. Furthermore, the claims' requirements of particular characteristics would be inherent to hepatocytes. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Accordingly Kaneko anticipate the claimed invention.



Art Unit: 1632

*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

Thaian N. Ton  
Patent Examiner  
Group 1632

**PETER PARAS, JR.**  
**PRIMARY EXAMINER**

